



Picloram Preliminary Work Plan

Registration Review: Initial Docket Case Number 0096

December 2013

Approved by:

Richard P. Keigwin, Jr.
Richard P. Keigwin, Jr.
Director
Pesticide Re-evaluation Division

Date:

12-13-2013

Picloram Preliminary Work Plan – Table of Contents

OVERVIEW	4
ANTICIPATED DATA NEEDS	5
STATUTORY AND REGULATORY AUTHORITY	7
CHEMICAL FACTS	7
USE AND USAGE INFORMATION	8
RECENT ACTIONS	9
ANTICIPATED RISK ASSESSMENTS FOR REGISTRATION REVIEW	9
TIMELINE	11
NEXT STEPS	12
Appendix – Additional Areas Considered in the Picloram Registration Review	13

References:

This Preliminary Work Plan summarizes the Environmental Protection Agency's current position based on the following documents:

1. *Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Picloram.* Dated December 3, 2013.
2. *Picloram. Human Health Assessment Scoping Document in Support of Registration Review* Dated December 12, 2013.
3. *Picloram: Tier I Review of Human Incidents.* Dated July 30, 2013
4. *BEAD Chemical Profile (BCP) for Registration Review: Picloram Salts and Esters Case (005101, 005102, and 005104).* Dated March 20, 2013.
5. *Picloram Case (005101, 005102, and 005104) Screening Level Usage Analysis.* Dated August 6, 2012.

6. *Human Health Effects Label Report*. Dated July 1, 2013.

7. *Environmental Fate and Effects Label Report*. Dated July 1, 2013.

These and other supporting documents for the picloram registration review case may be found in the docket EPA-HQ-OPP-2013-0740 at <http://www.regulations.gov>.

OVERVIEW

The docket for picloram is now open, initiating the first public comment period for this registration review (docket number EPA-HQ-OPP-2013-0740). This case includes the following three active ingredients: triisopropanolamine picloram (TIPA-salt), potassium picloram (K-salt), and picloram acid (picloram). Picloram is systemic herbicide registered for use for control of woody plants and a wide range of broadleaf weeds in range management programs. Picloram belongs to the pyridine family of herbicides and is a restricted use pesticide (RUP). Picloram may be combined with other herbicides, such as bromoxynil, 2,4-D, MCPA, triclopyr, and atrazine, to broaden the weed control spectrum. This Preliminary Work Plan (PWP) document explains what EPA's Office of Pesticide Programs knows about picloram, highlighting anticipated data and assessment needs, identifying the types of information that would be especially useful to the Agency in conducting the review, and providing an anticipated timeline for completing the registration review for picloram.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders. The Agency intends, by sharing this information in the docket, to inform the public of what it knows about picloram and what types of new data or other information would be helpful for the Agency to receive as it moves toward a decision on picloram. The Agency encourages all interested stakeholders to review the PWP and Appendix and to provide comments and additional information that will help the Agency's decision-making process for this chemical. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP and Appendix about which the Agency specifically seeks comments and information. Interested stakeholders could include: environmental non-profit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, residential, and other users of pesticides; or the public at large.

The Preliminary Work Plan begins by listing the anticipated data needs for picloram. Next, it discusses the statutory and regulatory authority for Registration Review. Then the document provides chemical facts, use and usage information, recent actions, the anticipated risk assessments, and a projected registration review timeline for picloram. Finally, the Appendix to this document includes identification and discussion of some areas that are considered generally in Registration Review along with some additional chemical case-specific information.

ANTICIPATED DATA NEEDS

Table 1 below summarizes anticipated data needs for picloram. For additional discussion of the anticipated data needs, see the *Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Picloram*, dated December 3, 2013 and *Picloram. Human Health Assessment Scoping Document in Support of Registration Review* dated December 12, 2013.

A number of picloram end-use products are co-formulated other active ingredient registered herbicides (i.e., 2,4-D, dicamba, fluroxypyr and/or triclopyr). The Agency has concerns that terrestrial plants may be more sensitive to these active ingredient co-formulations than to the picloram active ingredients alone. Therefore, the Agency anticipates requiring terrestrial plant toxicity data for these multiple active ingredient products. The Agency also has uncertainty in how picloram residues may act in compost. The Agency anticipates requiring data about how persistent picloram may be in compost, which should help inform the Agency's understanding of the potential risk to nontarget taxa posed by the application of composted material containing picloram residues.

Table 1: Anticipated Data Needs for the Picloram Registration Review

Guideline Number¹	Study Title¹	Test Material	Estimated Timeframe (Months from receipt of DCI)
835.1230	Adsorption/Desorption	TGAI	12
835.7100	Prospective ground water monitoring	TEP	24
SS	Dissipation Study in Compost	Compost sourced from material treated with TEP	12
850.2100	Avian oral toxicity (passerine species)	Picloram acid or K-salt	24
850.2300	Avian reproduction (bobwhite species)	Picloram acid or K-salt	12
850.4100	Seedling emergence	TEP w/TIPA-salt	12
850.4150	Vegetative vigor	TEP w/TIPA-salt	12
850.4500	Algal toxicity	TEP w/TIPA-salt	12
850.6100 ²	Environmental chemistry methods and associated independent laboratory validations for soil, water, and compost	TEP; Compost sourced from material treated with TEP	12
Anticipated Data Needs for Picloram End-Use Products Co-formulated with Another Herbicide			
850.4100 ³	Seedling emergence	TEP	12

Table 1: Anticipated Data Needs for the Picloram Registration Review

Guideline Number¹	Study Title¹	Test Material	Estimated Timeframe (Months from receipt of DCI)
850.4150 ³	Vegetative vigor	TEP	12

¹ On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 – Ecological Effects Tests – including renumbering and other designations or changes for some guideline studies. See “Final Test Guidelines; OCSPP 850 Series; Notice of Availability” 77 FR 38282, June 27, 2012. <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028>

² The Agency is currently reviewing environmental chemistry methods on soil and water. Independent laboratory validations are required for soil, water, and compost chemistry methods.

³ The DCI expected to be issued will provide that the test materials be representative of registered TEPs that are co-formulated with picloram TIPA-salt & another registered herbicide (e.g., 2,4-D; dicamba, fluroxypyr and/or triclopyr). When there are multiple products with dual active ingredients, the representative TEP used is the product with the highest percentages of active ingredient or is expected to result in the highest toxicity.

TGAI = technical grade active ingredient; TEP = typical end-use product

STATUTORY AND REGULATORY AUTHORITY

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided on EPA's website.¹

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop a Final Work Plan (FWP) and anticipated schedule for the registration review of picloram.

CHEMICAL FACTS

Table 2 provides a summary of the chemical facts for picloram.

Table 2: Chemical Facts for Picloram	
PC Codes	005101 (picloram acid), 005102 (TIPA-salt), 005104 (K-salt)
Case Number	0096
CAS Numbers	1918-02-1 (picloram acid), 6753-47-5 (TIPA-salt), 2545-60-0 (K-salt)
Year first registered	1964
Pesticide Type	Herbicide
Chemical class	Pyridine
Reregistration Eligibility Decision (RED)	August 1995
Tolerance Reassessment Eligibility Decision (TRED)	Not Applicable. Tolerance reassessment was conducted in 1999 as part of a registration action.

¹ http://www.epa.gov/oppsrrd1/registration_review/

Table 2: Chemical Facts for Picloram	
Cumulative group	Not Applicable. Picloram has not been identified as a member of a cumulative group that shares a common mechanism of toxicity.
40 CFR Citation	Tolerances for picloram are established in 40 CFR 180.292.
Pesticide Re-evaluation Division, Chemical Review Manager	Eric Miederhoff, miederhoff.eric@epa.gov, (703) 347-8028
Registration Division, Product Manager	Kable Davis, davis.kable@epa.gov, (703) 306-0415

USE AND USAGE INFORMATION

Table 3 summarizes the use and usage information for picloram. Please see the *BEAD Chemical Profile (BCP) for Registration Review: Picloram Salts and Esters Case (005101, 005102, and 005104)*, dated March 20, 2013, in the registration review docket for more details.

Table 3: Picloram Use and Usage Information	
Summary of Use	Picloram is systemic herbicide registered for use for control of woody plants and a wide range of broadleaf weed in range management programs. It can be applied as a pre- or post emergent treatment. In general, picloram is more toxic to broadleaf weeds than to grass species. Picloram belongs to the pyridine family of herbicides and is a restricted use product. Picloram may be combined with other herbicides such as bromoxynil, 2,4-D, MCPA, triclopyr, and atrazine to broaden the weed control spectrum.
Use Sites	<p>Agricultural use sites include: barley, fallow, oats, wheat, pastureland, and in forestry.</p> <p>Non-Agricultural use sites include: ornamentals, conservation reserve program land, rights of way, industrial sites, storage yards, fencerows, industrial areas, and hedgerows.</p>
Summary of Usage	From 1998 to 2011, ninety-eight percent of picloram usage was on pastureland. Picloram use declined by almost fifty percent during this time period. Other significant uses are on barley, fallow, and wheat.
Formulation Types	Picloram is formulated as emulsifiable, soluble concentrate, and as a solution-ready-to-use.
Application Methods	Picloram can be applied by broadcast, spot treatment as foliar (leaf), bare soil spray, as a basal bark treatment, and/or by air as broadcast spray.
Technical Registrants	Nufarm, Ltd.; Albaugh, Inc.; Dow Agrosiences, LLC; Celsius Property, B.V.

Table 3: Picloram Use and Usage Information	
No. of Registrations	34 Section 3 products ²
Restricted Use	Yes

Guidance for Commenters: Additional areas of *use and usage related information* requested for this registration review, and of particular interest to EPA, are described below:

- Certain picloram labels are unclear with respect to certain application parameters. Without further information, EPA expects to use conservative assumptions to approximate these parameters in order to conduct a quantitative risk assessment. However, the Agency will work with registrants to clarify information on picloram product labels, such as the maximum seasonal application rates and the maximum number of applications per year for labels with forest, conifer, and rooftop uses.
- Confirmation of the following label information: sites of application; formulations; application methods and equipment; maximum application rates; frequency of application, application intervals, and maximum number of applications per season; and geographic limitations on use.
- Use distribution (*e.g.*, acreage and geographical distribution of relevant use sites).
- Median and 90th percentile reported use rates (lbs ai/A) from usage data – national, state, and county.
- Typical application timing (date of first application and application intervals) – national, state, and county.
- Usage/use information for non-agricultural uses.
- Typical application interval (days).
- State or local use restrictions.
- Foreign technical registrants not listed above who supply technical picloram to the US market.

RECENT ACTIONS

There are no recent actions.

ANTICIPATED RISK ASSESSMENTS FOR REGISTRATION REVIEW

The most recent comprehensive human health risk assessment for picloram was completed on July 27, 1998 in preparation for a new use request. The most recent ecological and environmental fate risk assessment was completed in 1995 in support of the RED. Findings and conclusions from these risk assessments are summarized in the picloram Problem Formulation and Scoping Document.

During registration review, the Agency anticipates the need to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of picloram. For human health, EPA anticipates the need to conduct revised dietary and occupational risk

² Section 3 product labels can be obtained from the Pesticide Product Label System (PPLS) website (<http://oaspub.epa.gov/pestlabl/ppls.home>).

assessments during registration review. If toxicological endpoints or points of departure are revised based on the data that are anticipated to be required for registration review, they will be considered in the new assessments, as well as any changes to the standard operating procedures or default exposure assumptions.

Table 4 below summarizes the anticipated registration review risk assessments based on the EFED Problem Formulation and HED Scoping Document.

Table 4: Anticipated Risk Assessments for the Picloram Registration Review		
Type of Risk Assessment	Conduct?	Notes
Ecological and Environmental Fate		
Comprehensive ecological (species to be assessed include terrestrial and aquatic organisms), including endangered species	Yes	
Incidents	Will check for updates	For a discussion of reported ecological incidents for picloram, see pages 27-30 of the Problem Formulation.
Human Health		
Dietary		
Food	Yes	
Drinking water	Yes	
Occupational		
Handlers (mixers, loaders, applicators)	Yes	
Post-application	No	A post-application assessment is not required due to picloram's lack of dermal toxicity. A dermal post-application cancer assessment for the impurity HCB may be needed for registration review.
Residential		
Handlers	No	There are currently no registered residential uses for picloram.
Post-application	No	Although there are currently no registered residential uses, the need for a residential bystander exposure (spray drift and volatilization) risk assessment for picloram will be examined during registration review.
Other		
Aggregate	No	There are currently no registered residential uses for picloram.
Cumulative	No	Not Applicable. Picloram has not been identified as a member of a cumulative group that shares a common mechanism of toxicity.
Tolerances	No	

Incidents	Will check for updates	For a discussion of reported human incidents for picloram, see page 11 of the Scoping Document and the <i>Picloram: Tier I Review of Human Incidents</i> .
-----------	------------------------	--

Guidance for Commenters: Additional *ecological information* requested for this registration review, and of particular interest to EPA, is described below:

- The application of picloram to vegetative matter that is subsequently used as compost or animal feed has been found to retain picloram residues and affect non-target plants. The Agency is interested in additional information about this issue, such as incident reports and environmental fate data.

TIMELINE

EPA has created the following estimated timeline for the completion of the picloram registration review in Table 5 below.

Table 5: Projected Picloram Registration Review Timeline	
Activities	Estimated Date
Opening the Docket	
Open Docket and 60-day Public Comment Period	2013 – December
Close Public Comment	2014 – February
Case Development	
Final Work Plan	2014 – May
Issue DCI	2014 July – Sept.
Data Submission	2016 July – Sept.
60-day Public Comment Period for Draft Risk Assessments ^[1]	2018 Jan. – March
Registration Review Decision	
60-day Public Comment Period for Proposed Registration Review Decision	2018 July – Sept.
Registration Review Decision and Begin Post-Decision Follow-up	2019
Total (years)	6

^[1] The regulations governing Registration Review generally require the Agency to provide a public comment period of at least 30 calendar days for draft risk assessments; see 40 CFR Part 155.53(c). For conventional pesticides, the Agency plans to provide a 60 calendar day public comment period generally for draft risk assessments.

NEXT STEPS

After the 60-day public comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for the registration review of picloram.

Appendix – Additional Areas Considered in the Picloram Registration Review

PUBLIC COMMENTS AND FEEDBACK:

Guidance for Commenters: The areas below highlight topics of special interest to the Agency where your comments, data submissions, or reference to sources of additional information could be of particular use.

Trade Irritants:

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. The Agency will work to harmonize tolerances and international maximum residue limits (MRLs) and may modify tolerance levels to do so, when possible. **Growers and other stakeholders are asked to comment** on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality:

Picloram is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.³ In addition, no Total Maximum Daily Loads (TMDL) have been developed for picloram.⁴ More information on impaired water bodies and TMDLs can be found at the Agency's website.⁵ **The Agency invites submission of water quality data for this pesticide.** To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*⁶ in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice:

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to picloram compared to the general population. **Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.**

³ http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

⁴ http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

⁵ <http://www.epa.gov/owow/tmdl/>

⁶ http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

ENDANGERED SPECIES:

A risk assessment that supports a complete endangered species determination has not been conducted for picloram. The ecological risk assessment planned during registration review will allow the Agency to determine whether use of picloram has “no effect” or “may affect” federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide’s use “may affect” a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

ENDOCRINE DISRUPTOR SCREENING PROGRAM:

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for picloram, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), picloram is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013⁷ and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

⁷ See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

Picloram is on List 2. List 2 represents the next set of chemicals for which EPA intends to issue test orders/data call-ins in the near future. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.⁸

HUMAN STUDIES:

Past picloram risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED), and the Agricultural Reentry Task Force (ARTF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

⁸ <http://www.epa.gov/endo/>